

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NEW YORK CLAIMED
UNALLOWABLE FEDERAL
REIMBURSEMENT FOR SOME
MEDICAID PHYSICIAN-
ADMINISTERED DRUGS**

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February 2020
A-02-18-01011

Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: February 2020

Report No. A-02-18-01011

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. However, a prior OIG audit found that States did not always invoice and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether New York complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

How OIG Did This Audit

Our audit covered fee-for-service claims totaling \$92.6 million (Federal share) for physician-administered drugs paid between January 2015 and December 2017.

We used the Centers for Medicare & Medicaid Services' (CMS's) Medicare Part B crosswalk and the CMS Medicaid Drug File to identify single-source and multiple-source drugs. This information is based on published drug and biological pricing data and information submitted to CMS by manufacturers. Additionally, we determined whether the Healthcare Common Procedure Coding System (HCPCS) codes were published in CMS's top-20 multiple-source drug listing. HCPCS codes are used throughout the healthcare industry to standardize coding for medical procedures, services, products, and supplies.

New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

What OIG Found

New York did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, New York did not invoice manufacturers for rebates associated with \$3.3 million (Federal share) in single-source and top-20 multiple-source physician-administered drugs. Although New York's policies and procedures require the collection of utilization data necessary to invoice for rebates on all claims, its internal controls did not always ensure that the data were used to invoice manufacturers to secure rebates.

Further, New York did not submit the drug utilization data necessary to secure rebates for claims associated with all other physician-administered drugs. These drugs were included in claims totaling \$2.3 million (Federal share) that did not have drug codes and in claims totaling \$714,777 (Federal share) that contained drug codes.

What OIG Recommends and New York Comments

We recommend that New York refund to the Federal Government \$3.3 million for single-source and top-20 multiple-source physician-administered drugs and work with CMS to determine the unallowable portion of the \$3 million for other drug claims in question. We also made a procedural recommendation.

In written comments on our draft report, New York agreed with our recommended financial disallowance, partially agreed with our recommendation to work with CMS to determine the unallowable portion of the \$3 million for other drug claims in question, and agreed with our procedural recommendation. New York said that it believes it cannot obtain the drug codes for claims that are missing these codes because of the amount of time that has elapsed since the original date of service; therefore, it cannot invoice for these claims. In addition, New York described corrective actions it has taken or planned to take to address our recommendations.

After reviewing New York's comments, we maintain that our findings and recommendations are valid and that New York should work with CMS to invoice for all physician-administered drugs eligible for rebates, including claims without drug codes.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Audit	1
Objective	1
Background	1
Medicaid Drug Rebate Program	1
Physician-Administered Drugs	2
The State Agency’s Medicaid Drug Rebate Program	2
How We Conducted This Audit	3
FINDINGS	3
Federal and State Requirements	4
The State Agency Did Not Invoice Manufacturers for Rebates for Some Single-Source Physician-Administered Drugs	4
The State Agency Did Not Invoice Manufacturers for Rebates for Some Top-20 Multiple-Source Physician-Administered Drugs	4
The State Agency Did Not Invoice Manufacturers for Rebates for Other Physician-Administered Drugs	5
RECOMMENDATIONS	5
STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	6
APPENDICES	
A: Audit Scope and Methodology	7
B: Related Office of Inspector General Reports	9
C: Federal and State Requirements Related to Physician-Administered Drugs	12
D: State Agency Comments	14

INTRODUCTION

WHY WE DID THIS AUDIT

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset the Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, a prior Office of Inspector General audit found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix B lists previous OIG work on the Medicaid drug rebate program.) For this audit, we reviewed the New York State Department of Health's (State agency's) invoicing for rebates for physician-administered drugs for the period January 1, 2015, through December 31, 2017.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list of all covered outpatient drugs to CMS and to report each drug's average manufacturer price and, where applicable, best price.² On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States quarterly. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927 of the Act. To invoice for rebates, States capture drug utilization data that identifies, by the NDC, the number of units of each drug for which the States reimbursed Medicaid providers and

¹ *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 24, 2011.

² Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.⁴

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source and the top-20 multiple-source drugs.⁵ Beginning on January 1, 2007, CMS was responsible for publishing annually the list of the top-20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and to facilitate the collection of rebates for the drugs.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying Medicaid claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency also requires physician-administered drug claims to be submitted with the NDC of the product. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

³ HCPCS codes (sometimes referred to as J-Codes) are used throughout the healthcare industry to standardize coding for medical procedures, services, product, and supplies.

⁴ See, e.g., the Act § 1927(a)(7). In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the Food and Drug Administration. See, e.g., the Act § 1927(k)(7). Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

⁵ The term “top-20 multiple-source drugs” is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid (the Act § 1927(a)(7)(B)(i)).

HOW WE CONDUCTED THIS AUDIT

The State agency claimed \$168 million (\$92.6 million Federal share) for fee-for-service claims for physician-administered drugs paid between January 1, 2015, and December 31, 2017.

We used CMS's Medicare Part B crosswalk to identify, if possible, NDCs associated with each HCPCS code listed on claims from providers. We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs.⁶ Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. The State agency did not invoice for, and collect from manufacturers, rebates associated with \$6.2 million (\$3.3 million Federal share) in physician-administered drugs. Of this amount, \$5.9 million (\$3.2 million⁷ Federal share) was for single-source drugs, and \$270,592 (\$146,672 Federal share) was for top-20 multiple-source drugs. Although the State agency's policies and procedures require the collection of utilization data necessary to invoice for rebates on all claims, its internal controls did not always ensure that the data were used to invoice manufacturers to secure rebates.

Further, the State agency did not submit the utilization data necessary to secure rebates for claims associated with all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$4.2 million (\$2.3 million⁸ Federal share) that did not have NDCs. We were unable to determine whether the State

⁶ The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across healthcare programs.

⁷ The total was \$3,197,404.

⁸ The total was \$2,340,390.

agency was required to invoice for rebates for these claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$1.3 million (\$714,777 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$4.2 million (\$2.3 million Federal share) of claims that were submitted without NDCs and (2) whether the remaining \$1.3 million (\$714,777 Federal share) of claims could have been invoiced to the manufacturers for rebates.

FEDERAL AND STATE REQUIREMENTS

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act § 1927(a)(7)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing NDCs (42 CFR § 447.520).

The State requires physicians to report the NDC, the quantity of the drug administered or dispensed, and the unit of measure for the medication on the claim when requesting Medicaid reimbursement (*New York State Medicaid Update*, October 2008, volume 24, number 11 and August 2013, volume 29, number 9).

Appendix C contains Federal and State requirements related to physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$5.9 million (\$3.2 million Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of \$270,592 (\$146,672 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES FOR OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with other physician-administered drug claims, providers submitted some claims, totaling \$4.2 million (\$2.3 million Federal share), that did not have NDCs. We were unable to determine whether the State agency properly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Additionally, under the Medicaid drug rebate program, claims totaling \$1.3 million (\$714,777 Federal share), which contained NDCs, could have been eligible for rebates. These claims related to drugs that were non-top-20 multiple-source physician-administered drugs with NDCs. The State agency's obligation to invoice these claims for rebate is unclear.

Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$4.2 million (\$2.3 million Federal share) of claims that were submitted without NDCs and (2) whether the remaining \$1.3 million (\$714,777 Federal share) of other physician-administered drug claims should have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

RECOMMENDATIONS

We recommend that the New York Department of Health:

- refund to the Federal Government \$3,197,404 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$146,672 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine:
 - the unallowable portion of \$2,340,390 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$714,777 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims;
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2017; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency agreed with our first two recommendations (financial disallowance), partially agreed with our third recommendation, agreed with our fourth and fifth recommendations, and described corrective actions it has taken or planned to take.

Regarding our recommended financial disallowance, the State agency indicated that it will invoice for the drug rebates referenced in this audit and refund the Federal share of the collected rebates as appropriate. Regarding our third recommendation, the State agency stated that it will invoice for claims that contain NDCs and refund to the Federal Government its share for those claims. However, the State agency said that it believes it cannot obtain the NDCs for claims that are missing NDCs because of the amount of time that has elapsed since the original date of service; therefore, it cannot invoice for these claims. Further, the State agency stated that, effective July 1, 2019, it will require NDCs on all physician-administered drug claims. In response to our fourth and fifth recommendations, the State agency described steps it has taken to strengthen its internal controls and stated that it will continue to employ its vendor's expertise and systems to handle all concerns raised in this audit to ensure that drugs eligible for rebates are invoiced.

After reviewing the State agency's comments, we maintain that our findings and recommendations are valid and that the State agency should work with CMS to invoice for all physician-administered drugs eligible for rebates, including claims without NDCs. For example, the State agency could request missing NDCs from providers associated with claims that did not contain NDCs. The State agency's comments are included in their entirety as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed \$168,004,857 (\$92,626,072 Federal share) for fee-for-service claims for physician-administered drugs paid between January 1, 2015, and December 31, 2017.

Our audit objective did not require an understanding or assessment of the complete internal control structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's processes for reimbursing physician-administered drug claims and its process for claiming and obtaining Medicaid drug rebates for physician-administered drugs.

We conducted our fieldwork at the State agency's offices in Albany, New York.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- reviewed State requirements, including invoicing instructions for physician-administered drugs;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs;
- obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period;
- obtained claim details from the State agency's Medicaid Management Information System for all physician-administered drugs for the period January 1, 2015, through December 31, 2017;
- obtained the listing of 340B entities using the Health Resources and Services Administration's Office of Pharmacy Affairs Medicaid Exclusion File;⁹

⁹ Under the 340B drug-pricing program set forth in 42 U.S.C. § 256b, a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers. Examples of 340B entities are Medicare/Medicaid disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug-assistance programs. Drugs subject to discounts under the 340B drug-pricing program are not subject to rebates under the Medicaid drug rebate program (the Act § 1927(j) and 42 U.S.C. § 256b(a)(5)(A)).

- removed drug claims totaling \$156,365,674 (\$86,226,829 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate;
- reviewed the remaining drug claims totaling \$11,639,183 (\$6,399,243 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, we:
 - identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, NDCs associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs;
 - identified the top-20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing; and
 - identified the remaining drugs (those not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs; and
- discussed the results of our audit with State agency officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-02-16-01011</u>	8/30/2019
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-06-17-04001</u>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<u>A-07-18-06078</u>	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-18-00030</u>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-02-16-01012</u>	5/9/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-17-00038</u>	4/5/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02031</u>	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-13-06046</u>	12/22/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00013</u>	11/1/2017
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02028</u>	9/26/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02029</u>	9/26/2017

Report Title	Report Number	Date Issued
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02027</u>	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	1/5/2017
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00202</u>	12/30/2017
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00201</u>	12/22/2017
<i>California Did Not Bill Manufacturers for Rebates For Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<u>A-09-15-02035</u>	12/8/2017
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-15-06060</u>	8/18/2017
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/2017
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/2017
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/9/2017
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/2017
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/2017
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/7/2017

Report Title	Report Number	Date Issued
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/2015
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/7/2015
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/2015
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	4/24/2015
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/2011

APPENDIX C: FEDERAL AND STATE REQUIREMENTS RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 (which added section 1927 to the Act), became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services (HHS) and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit Medicaid Federal share for covered outpatient drugs administered by a physician unless the States collect the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires States to provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top-20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

FEDERAL REGULATIONS

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specify that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to invoice a manufacturer for rebates (42 CFR § 447.520).

STATE REQUIREMENT

The State agency follows the Federal DRA and requires physicians to report the 11-digit NDC, quantity of the drug administered or dispensed, and the unit of measure for the medication on the claim when requesting Medicaid reimbursement. The State agency's guidance further states that reimbursement is limited to drugs for which manufacturers have a signed rebate agreement with CMS (*New York State Medicaid Update*, October 2008, volume 24, number 11 and August 2013, volume 29, number 9).

APPENDIX D: STATE AGENCY COMMENTS



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

January 13, 2020

Ms. Brenda Tierney
Regional Inspector General for Audit Services
Department of Health and Human Services - Region II
Jacob Javits Federal Building
26 Federal Plaza
New York, New York 10278

Ref. No: **A-02-18-01011**

Dear Ms. Tierney:

Enclosed are the New York State Department of Health's comments on the United States Department of Health and Human Services, Office of Inspector General's Draft Audit Report **A-02-18-01011** entitled, "New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician- Administered Drugs."

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Sally Dreslin".

Sally Dreslin, M.S., R.N.
Executive Deputy Commissioner

Enclosure

cc: Marybeth Hefner
Diane Christensen
Elizabeth Misa
Geza Hrazdina
Dan Duffy
Erin Ives
Timothy Brown
Amber Rowan
Brian Kiernan
Jeffrey Hammond
Jill Montag
Michael Spitz
James DeMatteo
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**New York State Department of Health
Comments on the Department of Health and Human Services
Office of Inspector General Draft Audit Report A-02-18-01011 entitled,
"New York Claimed Unallowable Federal Reimbursement for Some
Medicaid Physician-Administered Drugs"**

The following are the New York State Department of Health's (Department) comments in response to the Department of Health and Human Services, Office of Inspector General (OIG) Draft Audit Report A-02-18-01011 entitled, "New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs."

General Comments:

DOH recognizes the OIG audit process as an opportunity to improve and strengthen policies and procedures. In November 2017, the Department secured an independent contractor to assume the invoicing process. The contractor has the expertise and systems to handle all concerns raised in this audit and if claims are found to have been missed, the Department will seek to bill where appropriate.

It should be noted that the Department issued invoices totaling \$1.3 billion (gross) during the three-year period covered by this audit for the fee-for-service program. The additional amount that the OIG believes should have been invoiced for during the three-year audit period amounts to less than one-percent of invoices issued.

Recommendation #1:

Refund to the Federal Government \$3,197,404 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

Response #1:

The Department will invoice for the drug rebates referenced above, as appropriate, and will refund the federal share of the collected rebates to CMS. The Department will continue to work with our vendor to ensure all appropriate drugs are invoiced.

Recommendation #2:

Refund to the Federal Government \$146,672 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

Response #2:

The Department will invoice for the drug rebates referenced above, as appropriate, and will refund the federal share of the collected rebates to CMS. The Department will continue to work with our vendor to ensure all appropriate drugs are invoiced.

Recommendation #3:

Work with CMS to determine:

- The unallowable portion of \$2,340,390 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and

- Whether the remaining \$714,777 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

Response #3:

In response to the first bullet, the Department believes the missing National Drug Codes (NDCs) cannot be obtained to appropriately invoice for these claims given the length of time that has lapsed from the original date of service. However, the Department has taken steps to ensure all claims for covered outpatient physician-administered drugs are invoiced going forward by requiring NDCs on all physician-administered drugs billed on the institutional claim form effective July 1, 2019. This announcement was sent in the March 2019 Medicaid Update:

https://www.health.ny.gov/health_care/medicaid/program/update/2019/2019-03.htm#ndc.

In response to the second bullet, for the other physician-administered drug claims with NDCs, the Department will invoice the claims, as appropriate, and upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

Recommendation #4:

Work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2017.

Response #4:

The Department has already taken steps to strengthen internal controls and will continue to employ its vendor's expertise and systems to handle all concerns raised in this audit to ensure that drugs eligible for rebates are invoiced.

Recommendation #5:

Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

Response #5:

The Department has already taken steps to strengthen internal controls and will continue to employ its vendor's expertise and systems to handle all concerns raised in this audit to ensure that drugs eligible for rebates are invoiced.